BECKMAN COULTER

JAN 1 5 2002

K013978

510(k) Summary
SYNCHRON® Systems Pancreatic Amylase Reagent

1.0 **Submitted By:**

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2.0 **Date Submitted:**

November 30, 2001

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Pancreatic Amylase Reagent

3.2 **Classification Name**

Amylase test system (21 CFR § 862.1070)

4.0 **Predicate Device(s):**

Beckman Coulter	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems Pancreatic Amylase (PAM) Reagent	SYNCHRON CX® Systems Pancreatic Amylase (PAMY) Reagent	Beckman Coulter	K934293

5.0 **Description:**

Beckman Coulter's Pancreatic Amylase (PAM) Reagent is a liquid stable, ready-to-use reagent designed for optimal performance on the SYNCHRON CX and LX Systems. The assay is intended for use in the quantitative determination of pancreas-specific amylase activity in human serum, plasma, or urine. The reagent kit contains two 60-test cartridges.

6.0 **Intended Use:**

Pancreatic Amylase (PAM) Reagent is intended for the quantitative determination of pancreas-specific amylase activity in human serum, plasma or urine on SYNCHRON Systems.

7.0 **Comparison to Predicate(s):**

Assay	Aspect/Characteristic	Comments
SIMILARITIES		
SYNCHRON® Systems PAM Reagent	Intended use	Same as Beckman Coulter SYNCHRON CX® PAMY Reagent
	Methodology	
	Antibody source (mouse)	
	Storage (+2°C to +8°C)	
	Shelf life	
	Sample type (serum, plasma, urine)	
	Sample size	
	Analytic range	
DIFFERENCES		
	Reagent formulation	**PAM**: ready to use liquid reagent **PAMY**: lyophilized components requiring preparation
	Reagent volume per test	**PAM**: 240 µl **PAMY**: 220 µl
	On-instrument stability	**PAM**: 30 days **PAMY**: 14 days
	Instrument platforms	**PAM**: CX and LX **PAMY**: CX only

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison and precision experiments that relate results obtained from the SYNCHRON Pancreatic Amylase (PAM) Assay to the Beckman Coulter's SYNCHRON CX Pancreatic Amylase (PAMY) Reagent.

Method Comparison Study Results*

Candidate Method	Sample Type	N	Slope	Intercept (U/L)	r	Predicate Method
SYNCHRON PAM Reagent	Serum	164	1.026	3.4	1.000	SYNCHRON CX PAMY Reagent
	Urine	122	1.021	0.9	1.000	

*Data shown was collected using SYNCHRON LX Systems. Equivalency between SYNCHRON CX and LX Systems has been established by correlation analysis.

Estimated SYNCHRON LX Systems PAM Imprecision

Sample	Mean (U/L)	S.D. (U/L)	%C.V.	N
Within-Run Imprecision				
Serum Control 1	64	0.8	1.3	80
Serum Control 2	410	3.3	0.8	80
Serum Control 3 (ORDAC)	772	8.3	1.1	80
Urine Control 1	148	1.0	0.7	80
Total Imprecision				
Serum Control1	64	2.7	4.3	80
Serum Control 2	410	4.5	1.1	80
Serum Control 3 (ORDAC)	772	10.5	1.4	80
Urine Control 1	148	1.9	1.3	80

The Summary of Safety and Effectiveness information for the SYNCHRON Systems Pancreatic Amylase Reagent is found in TAB 1 of this notice and is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 15 2002

Ms. Mary Beth Tang
Regulatory Affairs Specialist
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Box 8000
Brea, CA 92822-8000

Re: k013978
Trade/Device Name: SYNCHRON® Systems Pancreatic Amylase Reagent
Regulation Number: 21 CFR 862.1070
Regulation Name: Amylase test system
Regulatory Class: Class II
Product Code: JFJ
Dated: November 30, 2001
Received: December 3, 2001

Dear Ms. Tang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K013978**

Device Name: **SYNCHRON® Systems Pancreatic Amylase Reagent**

Indications for Use:

Pancreatic Amylase (PAM) Reagent is intended for the quantitative determination of pancreas-specific amylase activity in human serum, plasma, or urine on Beckman Coulter's SYNCHRON Systems by an immuno-inhibition method. Measurement of pancreatic amylase is useful in the diagnosis and treatment of pancreatitis.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013978

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

Optional Format 1-2-96